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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,055	10/22/2003	Craig D. Friedman	501438.20501	7247
54042 7590 05/02/2007 WOLF, BLOCK, SHORR AND SOLIS-COHEN LLP 250 PARK AVENUE 10TH FLOOR NEW YORK, NY 10177			EXAMINER HAGOPIAN, CASEY SHEA	
			ART UNIT 1615	PAPER NUMBER
			MAIL DATE 05/02/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/692,055	Applicant(s) FRIEDMAN ET AL.	
	Examiner Casey Hagopian	Art Unit 1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 January 2007.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-59, 61, 63-69, 72-76 and 78-83 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 13-59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-12, 61, 63-69, 72-74, 76 and 79-83 is/are rejected.
- 7) ☒ Claim(s) 75 and 78 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/26/06</u> . | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

Receipt is acknowledged of applicant's Amendment/Remarks filed 1/3/2007.

Currently, claims 1-59, 61, 63-69, 72-76 and 78-83 are pending and claims 1 and 13-59 are withdrawn.

### MAINTAINED REJECTIONS

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.** Claim 4 recites the limitation, "at least one therapeutic agent is contained within microspheres in the coating", however claim 2 from which it depends includes the limitation, "wherein said coating contains one or more therapeutic agents". It is unclear whether the "at least one therapeutic agent" in the microspheres in the coating of claim 4 is the "one or more therapeutic agents" in the coating of claim 2. There is no indication that the therapeutic agent of claim 2 is the same therapeutic agent of claim 4. Thus, the claim is vague and indefinite. Correction is respectfully requested.

***Response to Arguments***

Applicant's amendments, filed 1/3/2007, with respect to the provisional objection of claims 62, 70 and 77 under 37 CFR 1.75 have been fully considered and are persuasive. **The provisional objection of the claims has been withdrawn.**

Applicant's amendments, filed 1/3/2007, with respect to the objection of claims 77 and 78 have been fully considered and are persuasive. **The objection of the claims has been withdrawn.**

Applicant's amendments, filed 1/3/2007, with respect to the rejection of claims 2-12 and 60-78 under 35 USC 112, 1<sup>st</sup> paragraph (see paragraph 10 of Office Action dated 10/2/2006) have been fully considered and are persuasive. **The rejection of claims 2-12 and 60-78 under 35 USC 112, 1<sup>st</sup> paragraph has been withdrawn.**

Applicant's amendments, filed 1/3/2007, with respect to the rejections of claims 3 and 60 under 35 USC 112, 1<sup>st</sup> and 2<sup>nd</sup> paragraphs (see paragraphs 11 and 15 of Office Action dated 10/2/2006) have been fully considered and are persuasive. **The rejections of claims 3 and 60 under 35 USC 112, 1<sup>st</sup> and 2<sup>nd</sup> paragraphs have been withdrawn.**

Applicant's amendments, filed 1/3/2007, with respect to the rejection of claim 4 under 35 USC 112, 1<sup>st</sup> paragraph (see paragraph 12 of Office Action dated 10/2/2006) have been fully considered and are persuasive. **The rejection of claim 4 under 35 USC 112, 1<sup>st</sup> paragraph has been withdrawn.**

Applicant's amendments, filed 1/3/2007, with respect to the rejection of claim 60 under 35 USC 112, 1<sup>st</sup> paragraph (see paragraph 13 of Office Action dated 10/2/2006)

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have been fully considered and are persuasive. **The rejection of claim 60 under 35 USC 112, 1<sup>st</sup> paragraph has been withdrawn.**

Applicant's amendments, filed 1/3/2007, with respect to the rejections of claims 64 and 78 under 35 USC 112, 2<sup>nd</sup> paragraph (see paragraphs 17 and 18 of Office Action dated 10/2/2006) have been fully considered and are persuasive. **The rejections of claim 64 and 78 under 35 USC 112, 2<sup>nd</sup> paragraphs have been withdrawn.**

Applicant's amendments, filed 1/3/2007, with respect to the rejection of claim 4 under 35 USC 112, 2<sup>nd</sup> paragraph (see paragraph 16 of Office Action dated 10/2/2006) have been fully considered, but are not persuasive. **The rejection of claim 4 under 35 USC 112, 2<sup>nd</sup> paragraph has been maintained.** Claim 4 recites the limitation "wherein at least one therapeutic agent is contained with microspheres in the coating" and its base claim (claim 2) recites the limitation "wherein said coating contains one or more therapeutic agents". It is understood that the coating contains microspheres and the microspheres contain at least one therapeutic agent, however it is not clear that the "at least one therapeutic agent" in claim 4 and the "one or more therapeutic agents" in claim 2 are intended to be either one in the same or separate/different "therapeutic agents". Thus, the claim is still vague and indefinite.

Applicant's arguments with respect to claims 2-12 under 35 USC 102 have been considered but are moot in view of the new ground(s) of rejection. See below.

**NEW REJECTIONS**

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 2-12, 61, 63-69, 72-74, 76 and 79-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reich et al. (USPN 5,962,620) in view of Gould et al. (USPN 5,120,816).**

Reich teaches hydrophilic and hydrophobic polyether polyurethanes (title and abstract). The polyurethanes may be used to form a shaped structure or device including tubing, catheters, stents, and the like (col. 4, lines 59-60; col. 10, line 59; col. 15, lines 7-8) and the hydrophilic polymers may include drugs and enzymes, and may be coated over the polyurethanes (col. 3, lines 38-43 and col. 15, lines 10-12). Reich further teaches encapsulation of drugs in preferably, high viscosity hydrophilic polymers (col. 27, line 60 – col. 28, line 2). Reich also teaches the specific polymer polyurethane polycarbonate (col. 4, line 19; col. 10, lines 52; col. 16, lines 29). The polyether polyurethanes can also be formed into spreadable foams, gels and films (col. 1, lines 25-31).

Reich is silent to the limitation “foam” in regards to the scaffold.

Gould teaches that it is well known that water in a polyurethane precursor formation can cause foaming during polymerization, and that water in a hydrophobic polyurethane precursor formulation can assist in producing foams ranging from flexible to rigid (col. 2, lines 30-34).

It is well within the skilled artisan to optimize a composition (MPEP 2144.05 (II)). One of ordinary skill in the art would have been motivated to modify the amount of water during polymerization in order to produce a foamed substrate to the desired specifications and properties including compressibility and porosity. Furthermore, the

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limitations set out in claims 79-83 appear to all be dependent upon the degree of foaming that takes place, that is, pores size and void volume. Absent of unexpected results, a practitioner would have reasonably expected a foamed hydrophobic polyurethane scaffold. Thus, it would have been obvious to one of ordinary skill in the art to include the limitation "foam" as suggested by Gould.

### ***Conclusion***

Claims 2-12, 61, 63-69, 72-74, 76 and 79-83 have been rejected and claims 75 and 78 are objected to as being dependent on a rejected base claim. No claims are allowed.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Hagopian whose telephone number is 571-272-6097. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at 571-272-0588. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

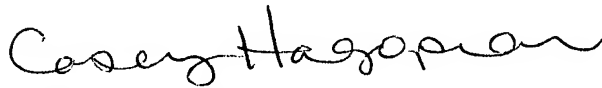
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.



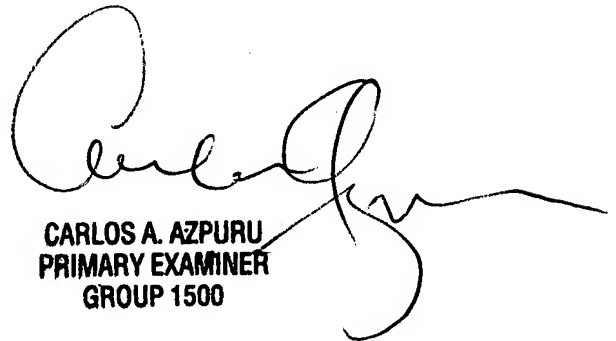
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Casey Hagopian  
Examiner  
Art Unit 1615



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